

(19)



Europäisches Patentamt
European Patent Office
Office européen des brevets



(11)

EP 0 959 930 B1

(12)

EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention
of the grant of the patent:
11.12.2002 Bulletin 2002/50

(21) Application number: **97901879.3**

(22) Date of filing: **22.01.1997**

(51) Int Cl.7: **A61M 25/01, A61F 5/44**

(86) International application number:
PCT/SE97/00096

(87) International publication number:
WO 97/026937 (31.07.1997 Gazette 1997/33)

(54) **HYDROPHILIC URINARY CATHETER HAVING A WATER-CONTAINING SACHET**
HYDROPHILER HARNKATHETER MIT WASSER ENTHALTENDEM BEUTEL
SONDE URINAIRE HYDROPHILE POURVUE D'UNE POCHE CONTENANT DE L'EAU

(84) Designated Contracting States:
AT BE CH DE DK ES FI FR GB GR IE IT LI NL PT
SE

(30) Priority: **25.01.1996 SE 9600276**

(43) Date of publication of application:
01.12.1999 Bulletin 1999/48

(60) Divisional application:
02008834.0 / 1 245 205

(73) Proprietor: **Astra Tech AB**
431 21 Mölndal (SE)

(72) Inventors:

- **ISRAELSSON, Anette**
S-412 76 Göteborg (SE)
- **PETTERSSON, Agneta**
S-416 54 Göteborg (SE)
- **UTAS, Jan**
S-434 96 Kungsbacka (SE)

(74) Representative: **Giver, Sören Bo et al**
Awapatent AB,
P.O. Box 113 94
404 28 Göteborg (SE)

(56) References cited:

GB-A- 2 284 764 **US-A- 2 856 932**
US-A- 3 648 704 **US-A- 3 967 728**

Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid. (Art. 99(1) European Patent Convention).

Description

[0001] The present invention relates to wetting apparatus for wetting of hydrophilic urinary catheters comprising a wetting receptacle which defines a wetting fluid receiving area which is adapted to receive a hydrophilic urinary catheter and a hydrophilic urinary catheter wetting fluid container having a discharge outlet movable from a closed position to an open position on application of a predetermined condition thereto to enable the wetting fluid to be discharged from the wetting fluid container into the wetting fluid receiving area for wetting of the hydrophilic urinary catheter. The present invention further relates to a fluid container of a type which may be used in such apparatus.

[0002] Intermittent self-catheterisation is widely employed by patients suffering from for example strictures or traumas in the urinary system as well as by paralysed patients to enable the patients to live a nearly normal home life. Urinary catheters supplied for intermittent self-catheterisation in general need to have a lubricant applied to the outer surfaces thereof to facilitate insertion into the urethra. For example, hydrophilic urinary catheters have a hydrophilic outer surface coating which should be wetted by a fluid such as water or saline for a certain time period prior to insertion thereof into the urethra of a patient for lubrication purposes.

[0003] Various methods for lubricating urinary catheters have been previously proposed, examples of which are given below.

[0004] Prior US patent No. 5209726 makes known a self-lubricating urinary catheter and a method for self-catheterisation. The catheter has an annular lubricant reservoir surrounding an inner tube having perforations. As the catheter is inserted into the urethra of a patient lubricant is forced from the reservoir into the inner tube and out into the urethra through a discharge outlet in the catheter. Lubrication of the outer surface of the catheter therefore only takes place as the catheter is being inserted into the urethra of the patient resulting in at least some initial discomfort for the patient on insertion of the catheter.

[0005] Prior US patent No. 3967728 makes known a catheter package comprising a urinary catheter and a rupturable, lubricant containing pouch. One edge of the pouch is located within the package adjacent to the tip of the catheter and the seal at that edge is made so that it ruptures when the pouch is squeezed thereby to lubricate the tip of the catheter. As only the tip of the catheter is lubricated the patient will still suffer discomfort on insertion of the catheter into the urethra.

[0006] Prior UK patent application publication No. 2284764 makes known a catheter and urine collection bag assembly comprising (i) a catheter having a shaft with a rounded tip, a drainage aperture in the tip and a flared portion to the rear of the shaft, and (ii) a urine collection bag within which the catheter is disposed and which at a forward end is formable with an aperture

which is sufficiently large to permit the tip and shaft of the catheter to pass through but small enough for the flared portion of the catheter to engage therewith to form a mechanical seal against leakage of urine. Once the catheter has been extended through the aperture it is ready to be inserted into the urethra of a patient. Urine is transported rearwardly through the catheter from the bladder of the patient for collection in the urine collection bag. It is disclosed that a separate, burstable container containing a lubricious substance may be included within the urine collection bag for lubricating the catheter. No details are given, however, of the construction of the container nor of the disposition of the container relative to the catheter.

[0007] Applicant's prior international patent application publication No. WO86/06284 discloses a wetting and storage device for a hydrophilic urinary catheter. A wetting pocket is provided, closed at one end so that it may be filled with a wetting liquid and a hydrophilic urinary catheter is then introduced into the pocket for wetting thereof. No liquid container, though, is provided in the device for releasing wetting liquid into the pocket immediately prior to use of the catheter. Wetting liquid for the pocket therefore has to be supplied separately by the patient. This is inconvenient because a sterile supply of wetting liquid is not necessarily always on hand to the patient and there is a marked possibility of spillage of the wetting liquid.

[0008] The hitherto proposed lubricating apparatus for urinary catheters discussed above have the drawback that they make no or inadequate provision for lubricating hydrophilic urinary catheters. As an example, the lubricating arrangements made known in US patent No. 3967728 and UK patent application publication No. 2284764 are for catheters of non-hydrophilic character, the lubricant therefore being a gel which is unsuited for lubricating a hydrophilic catheter. The prior lubricating apparatus therefore fail to provide an integrated supply of hydrophilic urinary catheter wetting fluid let alone an integrated supply of hydrophilic urinary catheter wetting fluid which on discharge results in wetting of the insertable length or substantially the insertable length of a hydrophilic urinary catheter prior to insertion of the catheter into the urethra of a patient.

[0009] Patients using hydrophilic urinary catheters accordingly require improved means for lubricating the catheters. The present invention therefore proposes to address this requirement. The present invention provides a wetting apparatus for wetting a hydrophilic urinary catheter as defined in claim 1.

[0010] By "integrated" is meant that the wetting fluid container and wetting receptacle are formed into a one-piece unit, that is to say, the wetting fluid container is supported on or by the wetting receptacle.

[0011] An "on tap" supply of lubricant for the hydrophilic urinary catheter is therefore available to the patient and the problem of possible spillage of the wetting fluid alleviated. Furthermore, an increased comfort on

insertion of the catheter into the urethra results due to the insertable length or substantially the insertable length of the catheter being lubricated prior to insertion.

[0012] In a preferred embodiment of the invention the wetting fluid is water or a saline solution.

[0013] In an embodiment of the invention such as hereinafter to be described the wetting fluid receiving area is an elongate pocket of length sufficient to accommodate at least the insertable length of the hydrophilic urinary catheter and the wetting fluid container is adapted to contain sufficient wetting fluid to fill the pocket to a level for wetting at least the insertable length of the hydrophilic urinary catheter.

[0014] In a preferred embodiment of the invention such as hereinafter to be described the wetting receptacle is a urine collection bag, the elongate pocket forms the forward portion of the urine collection bag and presents an open rear end and a weakened closed forward end which is removable upon application of a predetermined pressure thereto thereby to enable a portion of the hydrophilic urinary catheter comprising at least the insertable length thereof to be projected through the forward end of the pocket after wetting thereof for insertion into the urethra of a patient and the urine collection bag further comprises a urine collection chamber to the rear of the elongate pocket, the urine collection chamber having a forward end which is in fluid communication with the open rear end of the pocket and being adapted in use to collect urine transported rearwardly through the hydrophilic urinary catheter after insertion thereof into the urethra of the patient.

[0015] A typical sterilising agent which could be used for sterilising the wetting apparatus of the invention is ethylene oxide. Moreover, the fluid in the fluid container would normally be sterile. For these reasons, the wetting fluid container is preferably made of a material which is impermeable or substantially impermeable to ethylene oxide as well as the fluid contained therein. Non-limiting examples of materials satisfying this condition when the fluid is water or saline are aluminium foil, poly(vinylidene chloride) or a metallised film such as metallised poly(ethylene terephthalate).

[0016] In an embodiment of the invention such as hereinafter to be described the wetting fluid container is fully contained within the bounds of the wetting receptacle when in the operational position.

[0017] In an embodiment of the invention according to its first aspect such as hereinafter to be described the wetting fluid container is permanently fixed to the inner surface of the wetting receptacle.

[0018] In an alternative embodiment of the invention the wetting fluid container is an integrally formed compartment of the wetting receptacle.

[0019] In an embodiment of the invention such as hereinafter to be described the wetting receptacle is formed of a flexible material and the discharge outlet is able to be brought to the open position when in the operational position through application of a predeter-

mined force to the wetting fluid container through the material of the wetting receptacle.

[0020] In an embodiment of the invention according to its first aspect such as hereinafter to be described the wetting receptacle is provided with an inlet which is in fluid communication with the wetting fluid receiving area and the wetting fluid container is integrable with the inlet of the wetting receptacle in the operational position by insertion of at least a forward portion thereof in the inlet, the forward portion of the wetting fluid container presenting the discharge outlet.

[0021] In an embodiment of the invention such as hereinafter to be described the wetting fluid container is integrable with the wetting receptacle in the operational position through a friction fit between the wetting fluid container and the inlet of the wetting receptacle.

[0022] In an embodiment of the invention such as hereinafter to be described the fluid container comprises predetermined condition applying means for applying the predetermined condition to the discharge outlet to bring the discharge outlet to the open position.

[0023] In an embodiment of the invention such as hereinafter to be described the forward portion of the fluid container is positioned in the inlet of the receptacle when the fluid container is in the operational position, the fluid container comprises a rearward portion which in the operational position of the fluid container projects from the inlet of the receptacle and the rearward portion comprises at least a part of the predetermined condition applying means.

[0024] In an embodiment of the invention such as hereinafter to be described the discharge outlet comprises an area of weakness in the material of the forward portion of the fluid container which on application of a predetermined force thereto is able to be brought to the open position.

[0025] In an embodiment of the invention such as hereinafter to be described the at least a part of the predetermined condition applying means comprised of the rearward portion of the fluid container is a tab which on application of a predetermined pulling force thereto causes the predetermined force to be applied to the area of weakness in the material of the forward portion of the fluid container.

[0026] In an embodiment of the invention such as hereinafter to be described the area of weakness in the material of the forward portion of the fluid container is a tear line which is adapted to be torn on application of the predetermined pulling force to the tab. Preferably, the predetermined condition applying means further comprises holding means for holding the fluid container in the operational position against the action of the predetermined pulling force applied to the tab.

[0027] In an embodiment of the invention such as hereinafter to be described the receptacle is of a flexible material and the holding means is provided on the forward portion for gripping by a user through the material of the receptacle when the fluid container is in the oper-

ational position.

[0028] In an embodiment of the invention hereinafter to be described the forward portion of the fluid container presents a forward edge, the tear line extends rearwardly from the forward edge, the tab is a first tab which when the fluid container is in the operational position extends rearwardly from the forward edge of the forward portion on a first side of the tear line and being of such dimensions as to project from the inlet of the receptacle, the holding means for holding the fluid container in the operational position against the action of the pulling force applied to the first tab is a second tab which extends forwardly from the forward edge on a second opposite side of the tear line and application of a predetermined rearward pulling force on the first tab relative to the second tab when the fluid container is in the operational position causes the tear line to tear and the fluid to be dischargeable from the fluid container into the fluid receiving area of the receptacle:

[0029] In an embodiment of the invention such as hereinafter to be described the fluid container takes the form of a sachet.

[0030] In an embodiment of the invention the fluid container contains water or saline and is made of aluminium foil, poly(vinylidene chloride) or a metallised film such as metallised poly(ethylene terephthalate).

[0031] The present invention has the advantage of providing a safe, compact, sterile and disposable wetting apparatus for a hydrophilic urinary catheter which is easy to handle. This is due to the provision of a wetting fluid container component part which is adapted to cooperate with a wetting receptacle component part of the apparatus so as to be able to release its contents into the wetting receptacle to wet a hydrophilic urinary catheter placed therein under clean conditions, that is to say, without the need for touching of the catheter, fluid or inner surface of the wetting receptacle thereby avoiding or alleviating the risk of introducing contaminants.

[0032] By way of example embodiments of the invention will now be described with reference to the accompanying drawings in which:-

Fig. 1 shows a wetting apparatus according to a first embodiment of the invention comprising a urine collection bag and a wetting fluid container integrated therewith;

Fig. 2 shows a wetting apparatus according to a second embodiment of the invention comprising a urine collection bag and an unopened wetting fluid sachet in accordance with the invention integrated therewith in an operational position in the inlet of the urine collection bag;

Fig. 3 is an exploded view of the unopened sachet of the wetting apparatus shown in Fig. 2 in the operational position in the inlet of the urine collection bag;

Fig. 4 is a front view of the unopened sachet of the wetting apparatus shown in Fig. 2 in an extended configuration prior to insertion thereof into the inlet of the urine collection bag to the operational position;

Fig. 5 is a side view of the unopened sachet shown in Fig. 4;

Fig. 6 is a perspective view of the unopened sachet of the wetting apparatus shown in Fig. 2 in a retracted configuration ready for insertion into the inlet of the urine collection bag to the operational position;

Fig. 7 corresponds to Fig. 2 but with the wetting fluid sachet having been opened; and

Fig. 8 corresponds to Fig. 3 but with the wetting fluid sachet having been opened.

[0033] Referring first to Fig. 1, there is shown a wetting apparatus 10 according to the invention comprising a urine collection bag 1 of a transparent flexible plastics material. The bag 1 presents at the forward end thereof an elongate pocket 2 of depth sufficient to receive at least the insertable length of a hydrophilic urinary catheter 3. The urine collection bag 1 further defines to the rear of the pocket 2 a urine collection chamber 12 which is in fluid communication with the pocket 2. Further rearwardly is an inlet 14 to the urine collection bag 1 through which the hydrophilic urinary catheter 3 is able to be introduced into the bag 1.

[0034] As can be seen, the catheter 3 comprises a flared rearward portion 16 and an elongate shaft 18 which extends forwardly from the rearward portion 16 and terminates in a rounded tip 4 at the forward end thereof. The catheter 3 is provided with a lumen (not shown) which extends from an open end in the rearward portion 16 to a drainage aperture 5 in the tip 4.

[0035] A container in the form of a sachet 6 is secured to the inner surface of the urine bag 1. The sachet 6 contains sterile water or saline or other fluid suitable for wetting the hydrophilic urinary catheter 3 and is pierceable or otherwise openable, for example by applying a hand pressure, so as to release substantially all of the water or saline contained therein into the pocket 2 immediately prior to use of the catheter 3.

[0036] Typically, the urine collection bag 1 with integrated sachet 6 and, where pre-packaged therewith, the catheter 3 will be sterilised using ethylene oxide. Since the sachet 6 contains sterile water or saline there is no need for sterilising the contents of the sachet 6. Accordingly, the material of the sachet 6 is preferably impermeable to ethylene oxide and water. Non-limiting examples of materials meeting these requirements are poly(vinylidene chloride) (PVDC), aluminium foil laminates and metallised films, for example metallised poly(ethylene terephthalate). Other sterilisation processes could of

course be used instead, for example by irradiation in which case the fluid in the sachet 6 could be sterilised in situ at the same time as the rest of the components of the apparatus 10.

[0037] The volume of the sachet 6 is sufficient to release such an amount of water or saline into the pocket 2 to enable wetting of the insertable length of the catheter 3 immediately prior to use. By "insertable length" is meant at least that length of the elongate shaft 18 which is coated with a hydrophilic material, for example PVP, and inserted into the urethra of the patient. Typically, this will be 80-140mm for a female patient and 200-350mm for a male patient.

[0038] The holding time of the catheter 3 in the pocket 2 may vary within a broad range but will typically amount to at least 30 seconds.

[0039] The location of the sachet 6 inside the bag 1 is not critical as long as the sachet 6 releases its contents into the pocket 2. It is preferred, though, that the sachet 6 be disposed as close to the open end of the pocket 2 as possible. In this embodiment the sachet 6 is permanently fixed in position in the urine collection bag 1, for example by adhesion to the bag 1. It will be appreciated, however, that the sachet 6 could in fact be freely movable in the bag 1. The fundamental point is that the sachet 6 is within the bounds of the bag 1 so that the two components form an integrated unit.

[0040] In use, the catheter 3 is introduced into the bag 1 through the inlet 14 and the elongate shaft 18 manoeuvred into the pocket 2 as shown. The inlet 14 is then sealed, for example by tying a knot in the material defining the inlet 14 or by clamping the inlet 14 with a clamp. The sachet 6 is then opened, for example by applying a pressure thereto through the material of the bag 1, to release the wetting fluid into the pocket 2 and the catheter 3 left to soak for a predetermined duration in the wetting fluid to wet the hydrophilic outer surface thereof.

[0041] Alternately, the bag 1 may be provided with a closed end in place of the inlet with the catheter 3 pre-packaged inside the bag 1. An inlet 14 is preferred, though, where ethylene oxide is the sterilising agent as this provides a pathway for the ethylene oxide to enter and exit the inside of the bag 1.

[0042] After wetting of the catheter 3 for the predetermined duration, the bag 1 is turned upside down and the forwardmost portion of the pocket 2 torn off. The elongate shaft 18 of the catheter 3 is then manoeuvred through the opening in the forward end of the pocket 2 and into the urethra of the patient until the flared rearward portion 16 forms a mechanical seal connection with the opening. There is therefore no need to directly handle the catheter 3 for insertion thereof into the urethra which is to advantage as the outer surface of the catheter 3 will be slippery due to the wetting procedure and therefore difficult to grip and furthermore because the possibility of contamination of the catheter 3 at this stage is avoided.

[0043] Urine in the bladder of the patient is transported rearwardly through the lumen of the catheter 3 into the urine collection chamber 12. The catheter 3 is manoeuvred back inside the bounds of the bag 1 and the open end of the pocket 2 closed off for example by tying a knot with the material defining the pocket 2 or clamping the pocket 2 with a clamp. An opening can then be made in the urine collection chamber 12 for the collected urine to be poured away after which the bag 1 can be disposed of.

[0044] Turning now to Figs 2 and 3 of the drawings, there is shown an alternative wetting apparatus 110 according to the present invention. The wetting apparatus 110 comprises a urine collection bag 101 of a flexible transparent plastics material which corresponds to the urine collection bag 1 of the wetting apparatus 10 hereinbefore described with reference to Fig. 1 of the drawings. That is to say, the urine collection bag 101 has a downwardly extending elongate pocket 102 at the forward end, a urine collection chamber 112 rearwardly of and in fluid communication with the elongate pocket 102 and an inlet 114 to the bag 101 spaced further rearwardly.

[0045] Again as in the wetting apparatus 10 hereinbefore described with reference to Fig. 1, a hydrophilic urinary catheter 103 having a flared rearward portion 116, an elongate shaft 118 projecting forwardly from the rearward portion 116 and an open-ended lumen (not shown) which extends from the rear end of the rearward portion 116 to a drainage aperture 105 in the rounded tip 104 at the forward end of the catheter 103 is able to be inserted into the urine collection bag 101 through the inlet 114 such that preferably at least the insertable length of the catheter 103 is received in the pocket 102.

[0046] As can be seen more particularly by reference to Fig. 3, a wetting fluid containing sachet 106 is inserted into the inlet 114 to an operational position in which it is held in place by a friction fit. The sachet 106 has a forward portion 120 which in the operational position of the sachet 106 projects forwardly into the inlet 114 and a rearward portion 122 which in the operational position projects rearwardly out of the inlet 114.

[0047] The sachet 106 is preferably made of aluminium foil, particularly when ethylene oxide is the sterilising agent for the apparatus 110 and the sachet contains sterile water or saline solution. Where ethylene oxide is the sterilising agent for the apparatus 110 the fit of the sachet 106 in the inlet 114 is not so tight as to prevent ethylene oxide from entering and exiting the inside of the bag 101 and sterilising the inner surface of the bag 101 and outer surfaces of the sachet 106 and catheter 103. The wetting fluid is retained in the sachet 106 by peripheral sealing of the sachet 106 as shown.

[0048] Referring now to Figs 4 and 5, the forward portion 120 of the sachet 106 presents a forward edge 124. Extending rearwardly from the forward edge 124 is a tear line 126. Projecting forwardly from the forward edge 124 of the sachet 106 to one side of the tear line 126 is

a first tab 128. On the other side of the tear line 126 there is provided an elongate second tab 130 shown here in an extended position in which the second tab 130 projects forwardly from the forward edge 124.

[0049] As shown in Fig. 6, the elongate second tab 130 is movable about the forward edge 124 back on its self from the extended position shown in Figs 4 and 5 to a retracted position in which the second tab 130 extends rearwardly from the forward edge 124. When the second tab 130 is in the retracted position the sachet 106 is inserted into the inlet 114 to the operational position shown in Figs 2 and 3.

[0050] Returning now to Figs 2 and 3, it can be seen that the dimensions of the second tab 130 are such that when the sachet 106 is in the operational position a pulling portion 132 of the second tab 130 projects rearwardly from the inlet 114 of the urine collection bag 101 and forms a part of the rearward portion 122 of the sachet 106.

[0051] In Figs 7 and 8 there is shown the operation of the sachet 106 to release the contents of the sachet 106 into the pocket 102 to wet the hydrophilic outer coating of the catheter 103. The user grips the first tab 128 through the flexible transparent plastics material of the bag 101 and then pulls rearwardly on the pulling portion 132 of the second tab 130 which projects from the inlet 114 to cause the tear line 126 to be torn and the wetting fluid to be released into the pocket 102 to wet the catheter 103. Preferably, the sachet 106 contains sufficient wetting fluid for the pocket 102 to be filled to a level which results in the insertable length of the catheter 103 being wetted.

[0052] After release of the wetting fluid into the pocket 102 the sachet 106 is removed from the bag 101 and disposed of. The bag 101 and catheter 103 are then utilised in the manner hereinabove described for the wetting apparatus 10 shown in Fig. 1.

[0053] If need be, the bag 101 can be a closed bag with the sachet 106 and catheter 103 pre-packaged within the bag 101. In this instance, the construction of the bag 101 is such that the sachet 106 can be opened in the aforementioned manner through the material of the bag 101.

[0054] The wetting apparatus 110 described hereinabove with reference to Figs 2 to 8 has the advantage of *inter alia* (i) being environmentally friendly in the sense that where the sachet 106 is made of Al foil the sachet is able to be disposed of separately from the bag 101 thus facilitating recycling of the Al foil; and (ii) having a sachet 106 which can better withstand the cyclical pressures which are typically exerted on wetting apparatus when packaged and subjected to a sterilising process as a consequence of the sachet 106 not having to be opened through application of a direct pressure thereto through the material of the bag 101 in which case a significantly weakened sachet edge would be required as a high pressure could not be applied through the bag 101 without damaging the bag 101.

[0055] In the exemplary embodiments hereinabove described with reference to the Figures of drawings the supply of wetting fluid for wetting of the hydrophilic urinary catheter takes the form of a separate sachet integrated into the wetting receptacle. It will be appreciated by those versed in the art that according to the invention the supply could also take the form of an integrally formed chamber in the material of the wetting receptacle.

Claims

1. A wetting apparatus (10;110) for wetting a hydrophilic urinary catheter prior to use comprising a wetting receptacle (1;101) which defines a wetting fluid receiving area (2;102), wherein the wetting fluid receiving area forms an elongate pocket, and a hydrophilic urinary catheter (3;103) having a distal insertion end and arranged in said receptacle (1;101) wherein the elongate pocket accommodates the insertable length of the catheter, characterised in that the apparatus further comprises a wetting fluid container (6;106) containing a wetting fluid and being openable to enable the wetting fluid to be discharged from the wetting fluid container, that the wetting fluid container (6;106) is integrated with the wetting receptacle (1;101), that at least a discharge outlet of the wetting fluid container (6;106) is disposed within the bounds of the wetting receptacle (1;101) and arranged outside the elongate pocket and in a part of the wetting receptacle located opposite to said distal end of the catheter, that the discharge outlet of the wetting fluid container (6;106) is in fluid communication with the wetting fluid receiving area (2;102), and that opening of the discharge outlet of the wetting fluid container enables the wetting fluid to be discharged into the wetting fluid receiving area (2;102) and, thereby, to wet at least an insertable length of the hydrophilic urinary catheter (3;103).
2. A wetting apparatus according to claim 1, characterised in that the wetting fluid container (6;106) contains sufficient wetting fluid to fill the elongate pocket (2;102) to a level for wetting at least the insertable length of the hydrophilic urinary catheter (3;103).
3. A wetting apparatus according to claim 1 or 2; characterised in that the wetting receptacle is a urine collection bag (1;101), and that the elongate pocket (2;102) forms a forward portion thereof.
4. A wetting apparatus according to claim 3, characterised in that the urine collection bag further comprises a urine collection chamber (12;112) to the rear of the elongate pocket (2;102), said urine col-

lection chamber (12;112) having a volume greater than the volume of the elongate pocket (2;102).

5. A wetting apparatus according to claim 4, **characterised in that** the elongate pocket (2;102) of the urine collection bag presents an open rear end and a weakened closed forward end which is removable upon application of a predetermined pressure thereto thereby to enable a portion of the hydrophilic urinary catheter (3;103) comprising at least the insertable length thereof to be projected through a forward end of the elongate pocket (2;102) after wetting thereof for insertion into the urethra of a patient, and that the urine collection chamber (12;112) having a forward end which is in fluid communication with the open rear end of the elongate pocket (2;102) and being adapted in use to collect urine transported rearwardly through the hydrophilic urinary catheter (3;103) after insertion thereof into the urethra of the patient.
6. A wetting apparatus according to any one of the preceding claims, **characterised in that** the wetting fluid container (6;106) is made of aluminium foil, poly(vinylidene chloride) or a metallised film such as metallised poly(ethylene terephthalate).
7. A wetting apparatus according to any one of the preceding claims, **characterised in that** the wetting fluid container (6) is fully contained within the bounds of the wetting receptacle (1).
8. A wetting apparatus according to claim 7, **characterised in that** the wetting fluid container (6) is permanently fixed to an inner surface of the wetting receptacle (1).
9. A wetting apparatus according to claim 7, **characterised in that** the wetting fluid container is an integrally formed compartment of the wetting receptacle (1;101).
10. A wetting apparatus according to any one of the preceding claims, **characterised in that** the wetting receptacle (1;101) is formed of a flexible material and that the discharge outlet of the wetting fluid container (6;106) is able to be opened through application of a predetermined force to the wetting fluid container (6) through the material of the wetting receptacle (1).
11. A wetting apparatus according to any one of the claims 1-6, **characterised in that** the wetting receptacle (1;101) is provided with an inlet which is in fluid communication with the wetting fluid receiving area (2;102) and that the wetting fluid container (6;106) is integrated with the inlet of the wetting receptacle (1;101) by insertion of at least a forward por-

tion thereof in the inlet, the forward portion of the wetting fluid container (6;106) presenting the discharge outlet.

12. A wetting apparatus according to claim 11, **characterised in that** the wetting fluid container (6;106) is integrated with the inlet of the wetting receptacle (1;101) through a friction fit between the wetting fluid container (6;106) and the inlet of the wetting receptacle (1;101).
13. A wetting apparatus according to any one of the claims 11-12, **characterised in that** the wetting fluid container (6;106) comprises means for applying a predetermined condition to the discharge outlet to bring the discharge outlet of the wetting fluid container (6;106) to its open position.
14. A wetting apparatus according to any one of the claims 11-13, **characterised in that** the forward portion of the wetting fluid container (6;106) is positioned in the inlet of the wetting receptacle (1;101), and that the wetting fluid container (6;106) comprises a rearward portion which projects from the inlet of the wetting receptacle (1;101).
15. A wetting apparatus according to claim 14 as dependent on claim 13, **characterised in that** the rearward portion comprises at least a part of the means for applying the predetermined condition.
16. A wetting apparatus according to any one of claims 11 to 15, **characterised in that** the discharge outlet comprises an area of weakness in the material of the forward portion of the wetting fluid container (6;106) which on application of a predetermined force thereto is able to be brought to the open position.
17. A wetting apparatus according to claim 16 as appendant to claim 15, **characterised in that** at least a part of the means for applying the predetermined condition comprised of the rearward portion of the wetting fluid container (6;106) is a tab which on application of a predetermined pulling force thereto causes the predetermined force to be applied to the area of weakness in the material of the forward portion of the wetting fluid container (6;106).
18. A wetting apparatus according to claim 17, **characterised in that** the area of weakness in the material of the forward portion of the wetting fluid container (6;106) is a tear line which is adapted to be torn on application of the predetermined pulling force to the tab.
19. A wetting apparatus according to claim 18, **characterised in that** the means for applying the prede-

terminated condition further comprises holding means for holding the wetting fluid container (6;106) against the action of the predetermined pulling force applied to the tab.

20. A wetting apparatus according to claim 19, characterised in that the wetting receptacle (1;101) is of a flexible material and that the holding means is provided on the forward portion to be gripped by a user through the material of the wetting receptacle (1; 101).
21. A wetting apparatus according to claim 20, characterised in that the forward portion of the wetting fluid container (6;106) presents a forward edge, that the tear line extends rearwardly from the forward edge, that the tab is a first tab which extends rearwardly from the forward edge of the forward portion on a first side of the tear line and being of such dimensions as to project from the inlet of the wetting receptacle (1;101), that the holding means for holding the wetting fluid container (6;106) against the action of the pulling force applied to the first tab is a second tab which extends forwardly from the forward edge on a second opposite side of the tear line and that application of a predetermined rearward pulling force on the first tab relative to the second tab when causes the tear line to tear and the wetting fluid to discharge from the wetting fluid container (6; 106) into the wetting fluid receiving area (2;102) of the wetting receptacle (1;101).
22. A wetting apparatus according to any one of the preceding claims, characterised in that the wetting fluid container (106) takes the form of a sachet.
23. A wetting apparatus according to any one of the preceding claims, characterised in that the wetting fluid is water or a saline solution.
24. A wetting apparatus according to claim 23, characterised in that the wetting fluid container (6;106) is made of a material which is impermeable to ethylene oxide and water or saline solution.

Patentansprüche

1. Benetzungsvorrichtung (10; 110) zum Benetzen eines hydrophilen Harnkatheters vor der Verwendung mit einem Benetzungsbehältnis (1; 101), das einen Benetzungsfluidempfangsbereich (2; 102) definiert, wobei der Benetzungsfluidempfangsbereich eine längliche Tasche bildet, und einem hydrophilen Harnkatheter (3; 103), der ein distales Einführende aufweist und in dem Behältnis (1; 101) angeordnet ist, wobei in der länglichen Tasche die einführbare Länge des Katheters untergebracht ist, dadurch

gekennzeichnet, dass die Vorrichtung weiterhin einen Benetzungsfluidbehälter (6; 106) umfasst, der ein Benetzungsfluid enthält und geöffnet werden kann, damit das Benetzungsfluid aus dem Benetzungsfluidbehälter abgelassen werden kann, dass der Benetzungsfluidbehälter (6; 106) in dem Benetzungsbehältnis (1; 101) integriert ist, dass mindestens ein Ablassauslass des Benetzungsfluidbehälters (6; 106) innerhalb der Grenzen des Benetzungsbehältnisses (1; 101), außerhalb der länglichen Tasche und in einem gegenüber dem distalen Ende des Katheters angeordneten Teil des Benetzungsbehältnisses angeordnet ist, dass der Ablassauslass des Benetzungsfluidbehälters (6; 106) in Fluidverbindung mit dem Benetzungsfluidempfangsbereich (2; 102) steht und dass durch Öffnen des Ablassauslasses des Benetzungsfluidbehälters das Benetzungsfluid in den Benetzungsfluidempfangsbereich (2; 102) abgelassen und dadurch mindestens eine einführbare Länge des hydrophilen Harnkatheters (3; 103) benetzt werden kann.

2. Benetzungsvorrichtung nach Anspruch 1, dadurch gekennzeichnet, dass der Benetzungsfluidbehälter (6; 106) genügend Benetzungsfluid enthält, um die längliche Tasche (2; 102) soweit zu füllen, dass mindestens die einführbare Länge des hydrophilen Harnkatheters (3; 103) benetzt wird.
3. Benetzungsvorrichtung nach Anspruch 1 oder 2, dadurch gekennzeichnet, dass es sich bei dem Benetzungsbehältnis um einen Harnsammelbeutel (1; 101) handelt und dass die längliche Tasche (2; 102) dessen vorderen Teil bildet.
4. Benetzungsvorrichtung nach Anspruch 3, dadurch gekennzeichnet, dass der Harnsammelbeutel weiterhin eine Harnsammelkammer (12; 112) am hinteren Teil der länglichen Tasche (2; 102) umfasst, wobei das Volumen der Harnsammelkammer (12; 112) größer ist als das der länglichen Tasche (2; 102).
5. Benetzungsvorrichtung nach Anspruch 4, dadurch gekennzeichnet, dass die längliche Tasche (2; 102) des Harnsammelbeutels ein offenes Hinterende und ein geschwächtes geschlossenes Vorderende aufweist, das durch Ausübung eines vorbestimmten Drucks darauf entfernbar ist, wodurch ein Abschnitt des hydrophilen Harnkatheters (3; 103) mit mindestens dessen einführbare Länge durch ein Vorderende der länglichen Tasche (2; 102) nach Benetzung vorgeschoben und in die Urethra eines Patienten eingeführt werden kann, und dass die Harnsammelkammer (12; 112) ein mit dem offenen Hinterende der länglichen Tasche (2; 102) in Fluidverbindung stehendes Vorderende aufweist und in

- ihre im Gebrauch nach hinten durch den hydrophilen Harnkatheter (3; 103) transportierter Harn gesammelt werden kann, nachdem dieser in die Urethra des Patienten eingeführt worden ist.
6. Benetzungsvorrichtung nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet**, dass der Benetzungsfuidbehälter (6; 106) aus Aluminiumfolie, Polyvinylidenchlorid oder einer metallisierten Schicht wie metallisiertem Polyethylen-terephthalat hergestellt ist. 5
 7. Benetzungsvorrichtung nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet**, dass der Benetzungsfuidbehälter (6) ganz innerhalb der Grenzen des Benetzungsbehältnisses (1) enthalten ist. 10
 8. Benetzungsvorrichtung nach Anspruch 7, **dadurch gekennzeichnet**, dass der Benetzungsfuidbehälter (6) dauerhaft an einer Innenfläche des Benetzungsbehältnisses (1) befestigt ist. 15
 9. Benetzungsvorrichtung nach Anspruch 7, **dadurch gekennzeichnet**, dass es sich bei dem Benetzungsfuidbehälter um ein einstückig gebildetes Fach des Benetzungsbehältnisses (1; 101) handelt. 20
 10. Benetzungsvorrichtung nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet**, dass das Benetzungsbehältnis (1; 101) aus einem flexiblen Material gebildet ist und dass der Ablassauslass des Benetzungsfuidbehälters (6; 106) durch Ausübung einer vorbestimmten Kraft auf den Benetzungsfuidbehälter (6) durch das Material des Benetzungsbehältnisses (1) hindurch geöffnet werden kann. 25
 11. Benetzungsvorrichtung nach einem der Ansprüche 1 - 6, **dadurch gekennzeichnet**, dass das Benetzungsbehältnis (1; 101) mit einem in Fluidverbindung mit dem Benetzungsfuidempfangsbereich (2; 102) stehenden Einlass versehen ist und dass der Benetzungsfuidbehälter (6; 106) mit dem Einlass des Benetzungsbehältnisses (1; 101) integriert ist, indem mindestens ein Vorderabschnitt davon in den Einlass eingeführt wird, wobei der Vorderabschnitt des Benetzungsfuidbehälters (6; 106) den Ablassauslass aufweist. 30
 12. Benetzungsvorrichtung nach Anspruch 11, **dadurch gekennzeichnet**, dass der Benetzungsfuidbehälter (6; 106) durch eine Presspassung zwischen dem Benetzungsfuidbehälter (6; 106) und dem Einlass des Benetzungsbehältnisses (1; 101) mit dem Einlass des Benetzungsbehältnisses (1; 101) integriert ist. 35
 13. Benetzungsvorrichtung nach Anspruch 11 oder 12, **dadurch gekennzeichnet**, dass der Benetzungsfuidbehälter (6; 106) eine Einrichtung zur Ausübung eines vorbestimmten Zustands auf den Ablassauslass, um den Ablassauslass des Benetzungsfuidbehälters (6; 106) in seine offene Stellung zu bringen, umfasst. 40
 14. Benetzungsvorrichtung nach einem der Ansprüche 11 - 13, **dadurch gekennzeichnet**, dass der Vorderabschnitt des Benetzungsfuidbehälters (6; 106) im Einlass des Benetzungsbehältnisses (1; 101) angeordnet ist und dass der Benetzungsfuidbehälter (6; 106) einen Hinterabschnitt umfasst, der aus dem Einlass des Benetzungsbehältnisses (1; 101) vorsteht. 45
 15. Benetzungsvorrichtung nach Anspruch 14 in Abhängigkeit von Anspruch 13, **dadurch gekennzeichnet**, dass der Hinterabschnitt mindestens einen Teil der Einrichtung zur Ausübung des vorbestimmten Zustands umfasst. 50
 16. Benetzungsvorrichtung nach einem der Ansprüche 11 bis 15, **dadurch gekennzeichnet**, dass der Ablassauslass einen Schwächebereich im Material des Vorderabschnitts des Benetzungsfuidbehälters (6; 106) umfasst, der bei Ausübung einer vorbestimmten Kraft darauf in die offene Stellung gebracht werden kann. 55
 17. Benetzungsvorrichtung nach Anspruch 16 in Abhängigkeit von Anspruch 15, **dadurch gekennzeichnet**, dass es sich bei mindestens einem Teil der Einrichtung zur Ausübung des vorbestimmten Zustands, den der Hinterabschnitt des Benetzungsfuidbehälters (6; 106) umfasst, um eine Lasche handelt, durch die bei Ausübung einer vorbestimmten Zugkraft darauf veranlasst wird, dass die vorbestimmte Kraft auf den Schwächebereich im Material des Vorderabschnitts des Benetzungsfuidbehälters (6; 106) ausgeübt wird.
 18. Benetzungsvorrichtung nach Anspruch 17, **dadurch gekennzeichnet**, dass es sich bei dem Schwächebereich im Material des Vorderabschnitts des Benetzungsfuidbehälters (6; 106) um eine Reißlinie handelt, die bei der Ausübung der vorbestimmten Zugkraft auf die Lasche aufgerissen werden kann.
 19. Benetzungsvorrichtung nach Anspruch 18, **dadurch gekennzeichnet**, dass die Einrichtung zur Ausübung des vorbestimmten Zustands weiterhin eine Halteeinrichtung zum Halten des Benetzungsfuidbehälters (6; 106) gegen die Wirkung der auf die Lasche ausgeübten vorbestimmten Zugkraft umfasst.

20. Benetzungsvorrichtung nach Anspruch 19, **dadurch gekennzeichnet, dass** das Benetzungsbehältnis (1; 101) aus einem flexiblen Material besteht und dass die Halteeinrichtung am Vorderabschnitt vorgesehen ist und von einem Benutzer durch das Material des Benetzungsbehältnisses (1; 101) hindurch ergriffen wird.

21. Benetzungsvorrichtung nach Anspruch 20, **dadurch gekennzeichnet, dass** der Vorderabschnitt des Benetzungsfuidbehälters (6; 106) eine Vorderkante aufweist, dass sich die Reißlinie von der Vorderkante nach hinten erstreckt, dass es sich bei der Lasche um eine erste Lasche handelt, die sich von der Vorderkante des Vorderabschnitts auf einer ersten Seite der Reißlinie nach hinten erstreckt und so groß ist, dass sie aus dem Einlass des Benetzungsbehältnisses (1; 101) vorsteht, dass es sich bei der Halteeinrichtung zum Halten des Benetzungsfuidbehälters (6; 106) gegen die Wirkung der auf die erste Lasche ausgeübten Zugkraft um eine zweite Lasche handelt, die sich von der Vorderkante auf einer zweiten gegenüberliegenden Seite der Reißlinie nach vorne erstreckt und dass durch Ausübung einer vöbestimmten rückwärtigen Zugkraft auf die erste Lasche bezüglich der zweiten Lasche dann veranlasst wird, dass die Reißlinie aufreißt und das Benetzungsfuid aus dem Benetzungsfuidbehälter (6; 106) in den Benetzungsfuidempfangsbereich (2; 102) des Benetzungsbehältnisses (1; 101) abgelassen wird.

22. Benetzungsvorrichtung nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** der Benetzungsfuidbehälter (106) die Form eines Beutels hat.

23. Benetzungsvorrichtung nach einem der vorhergehenden Ansprüche, **dadurch gekennzeichnet, dass** es sich bei dem Benetzungsfuid um Wasser oder eine Kochsalzlösung handelt.

24. Benetzungsvorrichtung nach Anspruch 23, **dadurch gekennzeichnet, dass** der Benetzungsfuidbehälter (6; 106) aus einem Material besteht, das undurchlässig für Ethylenoxid und Wasser oder Kochsalzlösung ist.

Revendications

1. Appareil de mouillage (10 ; 110) pour mouiller une sonde urinaire hydrophile avant l'emploi, comprenant un réceptacle de mouillage (1 ; 101) qui définit une zone de réception de fluide de mouillage (2 ; 102), la zone de réception de fluide de mouillage formant une poche allongée, et une sonde urinaire hydrophile (3 ; 103) qui possède une extrémité d'in-

sertion distale et qui est arrangée dans ledit réceptacle (1 ; 101), dans lequel la longueur apte à s'insérer vient se loger dans la poche allongée, **caractérisé en ce que** l'appareil comprend en outre un récipient de fluide de mouillage (6 ; 106) contenant un fluide de mouillage et qui peut s'ouvrir pour permettre au fluide de mouillage de s'évacuer du récipient de fluide de mouillage, **en ce que** le récipient de fluide de mouillage (6 ; 106) est intégré dans le réceptacle de mouillage (1 ; 101), **en ce qu'**au moins une sortie d'évacuation du récipient de fluide de mouillage (6 ; 106) est disposée dans les limites du réceptacle de mouillage (1 ; 101) et est arrangée à l'extérieur de la poche allongée et dans la partie du réceptacle de mouillage disposée à l'opposé de ladite extrémité distale de la sonde, **en ce que** la sortie d'évacuation du récipient de fluide de mouillage (6 ; 106) établit une communication de fluide avec la zone de réception de fluide de mouillage (2 ; 102), et **en ce que** l'ouverture de la sortie d'évacuation du récipient de fluide de mouillage permet d'évacuer le fluide de mouillage dans la zone de réception de fluide de mouillage (2 ; 102) pour ainsi mouiller au moins une longueur de la sonde urinaire hydrophile (3 ; 103) apte à s'insérer.

2. Appareil de mouillage selon la revendication 1, **caractérisé en ce que** le récipient de fluide de mouillage (6 ; 106) contient une quantité suffisante de fluide de mouillage pour remplir la poche allongée (2 ; 102) jusqu'à un niveau qui permet de mouiller au moins la longueur de la sonde urinaire hydrophile (3 ; 103) apte à s'insérer.

3. Appareil de mouillage selon la revendication 1 ou 2, **caractérisé en ce que** le réceptacle de mouillage est un sac de récolte de l'urine (1 ; 101) et **en ce que** la poche allongée (2 ; 102) forme la portion avant dudit sac.

4. Appareil de mouillage selon la revendication 3, **caractérisé en ce que** le sac de récolte de l'urine comprend en outre une chambre de récolte de l'urine (12 ; 112) à l'arrière de la poche allongée (2 ; 102), le volume de ladite chambre de récolte de l'urine (12 ; 112) étant supérieur au volume de la poche allongée (2 ; 102).

5. Appareil de mouillage selon la revendication 4, **caractérisé en ce que** la poche allongée (2 ; 102) dudit sac de récolte de l'urine présente une extrémité arrière ouverte et une extrémité avant fermée affaiblie qui peut être retirée lorsque s'y exerce une pression prédéterminée pour permettre à la portion de la sonde urinaire hydrophile (3 ; 103), comprenant au moins sa longueur apte à s'insérer, de faire saillie à travers l'extrémité avant de la poche allongée (2 ; 102), après son mouillage, à des fins d'in-

- sertion dans l'urètre d'un patient, et en ce que la chambre de récolte de l'urine (12 ; 112) possède une extrémité avant qui établit une communication de fluide avec l'extrémité arrière ouverte de la poche allongée (2 ; 102) et qui est conçue, en état de marche, pour récolter de l'urine transportée vers l'arrière à travers la sonde urinaire hydrophile (3 ; 103) après son insertion dans l'urètre du patient.
6. Appareil de mouillage selon l'une quelconque des revendications précédentes, **caractérisé en ce que le récipient de fluide de mouillage (6 ; 106) est réalisé à l'aide d'une feuille d'aluminium, de chlorure de polyvinylidène ou encore d'un film métallisé tel que du polyéthylène téréphthalate métallisé.**
 7. Appareil de mouillage selon l'une quelconque des revendications précédentes, **caractérisé en ce que le récipient de fluide de mouillage (6) est complètement renfermé dans les limites du réceptacle de mouillage (1).**
 8. Appareil de mouillage selon la revendication 7, **caractérisé en ce que le récipient de fluide de mouillage (6) est fixé en permanence à la surface interne du réceptacle de mouillage (1).**
 9. Appareil de mouillage selon la revendication 7, **caractérisé en ce que le récipient de fluide de mouillage est un compartiment faisant intégralement partie du récipient de mouillage (1 ; 101).**
 10. Appareil de mouillage selon l'une quelconque des revendications précédentes, **caractérisé en ce que le réceptacle de mouillage (1 ; 101) est réalisé à partir d'une matière flexible, et en ce que la sortie d'évacuation du récipient de fluide de mouillage (6 ; 106) est à même de s'ouvrir lorsqu'une force prédéterminée s'exerce sur le récipient de fluide de mouillage (6) à travers la matière du réceptacle de mouillage (1).**
 11. Appareil de mouillage selon l'une quelconque des revendications 1 à 6, **caractérisé en ce que le réceptacle de mouillage (1 ; 101) est muni d'une entrée qui établit une communication de fluide avec la zone de réception de fluide de mouillage (2 ; 102), et en ce que le récipient de fluide de mouillage (6 ; 106) est intégré dans l'entrée du réceptacle de mouillage (1 ; 101) par l'insertion d'au moins sa portion avant dans l'entrée, la portion avant du récipient de fluide de mouillage (6 ; 106) présentant la sortie d'évacuation.**
 12. Appareil de mouillage selon la revendication 11, **caractérisé en ce que le récipient de fluide de mouillage (6 ; 106) est intégré dans l'entrée du réceptacle de mouillage (1 ; 101) via un ajustage par**
- friction entre le récipient de fluide de mouillage (6 ; 106) et l'entrée du réceptacle de mouillage (1 ; 101).
13. Appareil de mouillage selon l'une quelconque des revendications 11 - 12, **caractérisé en ce que le récipient de fluide de mouillage (6 ; 106) comprend un moyen pour appliquer un état prédéterminé à la sortie d'évacuation dans le but d'amener la sortie d'évacuation du récipient de fluide de mouillage (6 ; 106) dans sa position ouverte.**
 14. Appareil de mouillage selon l'une quelconque des revendications 11 à 13, **caractérisé en ce que la portion avant du récipient de fluide de mouillage (6 ; 106) est disposée dans l'entrée du réceptacle de mouillage (1 ; 101), et en ce que le récipient de fluide de mouillage (6 ; 106) comprend une portion arrière qui fait saillie par rapport à l'entrée du réceptacle de mouillage (1 ; 101).**
 15. Appareil de mouillage selon la revendication 14 telle qu'elle dépend de la revendication 13, **caractérisé en ce que la portion arrière comprend au moins une partie du moyen pour appliquer l'état prédéterminé.**
 16. Appareil de mouillage selon l'une quelconque des revendications 11 à 15, **caractérisé en ce que la sortie d'évacuation comprend une zone d'affaiblissement dans la matière de la portion avant du récipient de fluide de mouillage (6 ; 106) qui, lorsqu'on y exerce une force prédéterminée, est à même de prendre la position ouverte.**
 17. Appareil de mouillage selon la revendication 16 telle qu'elle dépend de la revendication 15, **caractérisé en ce qu'au moins une partie du moyen pour appliquer l'état prédéterminé comprend la portion arrière du récipient de fluide de mouillage (6 ; 106) est une patte qui, lorsqu'on y exerce une force de traction prédéterminée, fait en sorte d'appliquer la force prédéterminée sur la zone d'affaiblissement de la matière de la portion avant du récipient de fluide de mouillage (6 ; 106).**
 18. Appareil de mouillage selon la revendication 17, **caractérisé en ce que la zone d'affaiblissement dans la matière de la portion avant du récipient de fluide de mouillage (6 ; 106) est une ligne d'arrachage qui est conçue pour être arrachée lorsqu'on exerce la force de traction prédéterminée sur la patte.**
 19. Appareil de mouillage selon la revendication 18, **caractérisé en ce que le moyen pour appliquer l'état prédéterminé comprend en outre un moyen de retenue pour retenir le récipient de fluide de mouillage (6 ; 106) à l'encontre de l'action exercée par la force de traction prédéterminée sur la patte.**

20. Appareil de mouillage selon la revendication 19, caractérisé en ce que le réceptacle de mouillage (1 ; 101) est constitué de matière flexible et en ce que le moyen de retenue est prévu, sur sa portion avant, pour être saisi par un utilisateur via la matière du réceptacle de mouillage (1 ; 101). 5
21. Appareil de mouillage selon la revendication 20, caractérisé en ce que la portion avant du récipient de fluide de mouillage (6 ; 106) présente un bord avant, en ce que la ligne d'arrachage s'étend vers l'arrière à partir du bord avant, en ce que la patte est une première patte qui s'étend vers l'arrière à partir du bord avant de la portion avant sur un premier côté de la ligne d'arrachage et qui possède des dimensions telles qu'elle fait saillie par rapport à l'entrée du réceptacle de mouillage (1 ; 101), en ce que le moyen de retenue pour retenir le récipient de fluide de mouillage (6 ; 106) à l'encontre de l'action exercée par la force de traction sur la première patte est une deuxième patte qui s'étend vers l'avant à partir du bord avant sur le deuxième côté opposé de la ligne d'arrachage, et en ce que le fait d'exercer une force de traction prédéterminée orientée vers l'arrière sur la première patte par rapport à la deuxième patte donne lieu à l'arrachage de la ligne d'arrachage et l'évacuation de fluide de mouillage depuis le récipient de fluide de mouillage (6 ; 106) jusque dans la zone de réception de fluide de mouillage (2 ; 102) du réceptacle de mouillage (1 ; 101). 10 15 20 25 30
22. Appareil de mouillage selon l'une quelconque des revendications précédentes, caractérisé en ce que le récipient de fluide de mouillage (106) prend la forme d'un sachet 35
23. Appareil de mouillage selon l'une quelconque des revendications précédentes, caractérisé en ce que le fluide de mouillage est de l'eau ou une solution salée. 40
24. Appareil de mouillage selon la revendication 23, caractérisé en ce que le récipient de fluide de mouillage (6 ; 106) est réalisé en une matière qui est imperméable à l'oxyde d'éthylène et à l'eau ou à la solution salée. 45

50

55

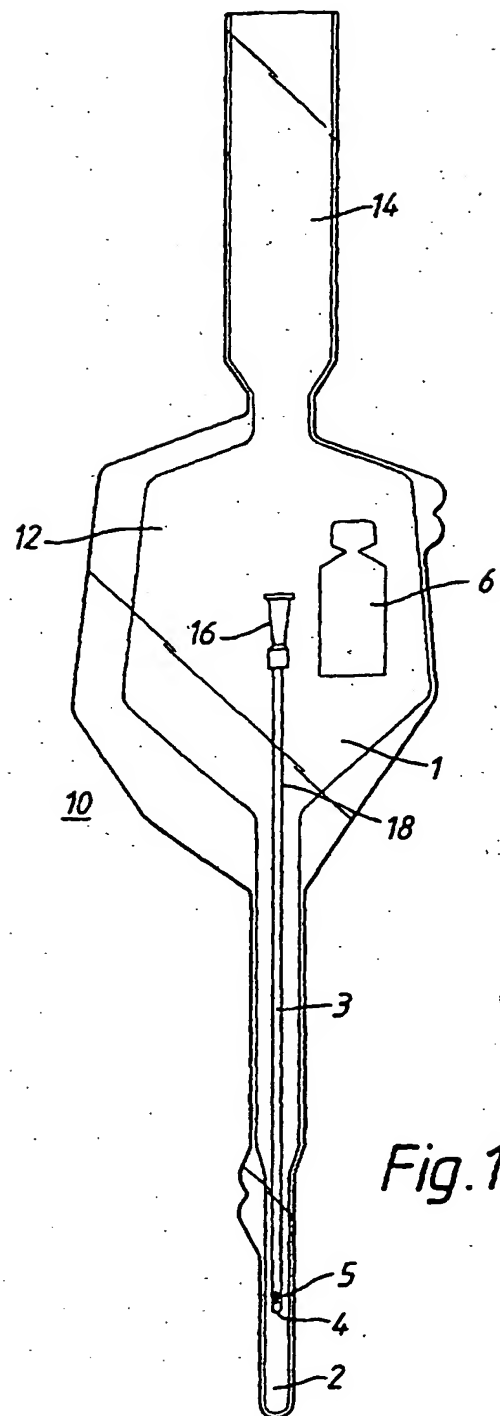
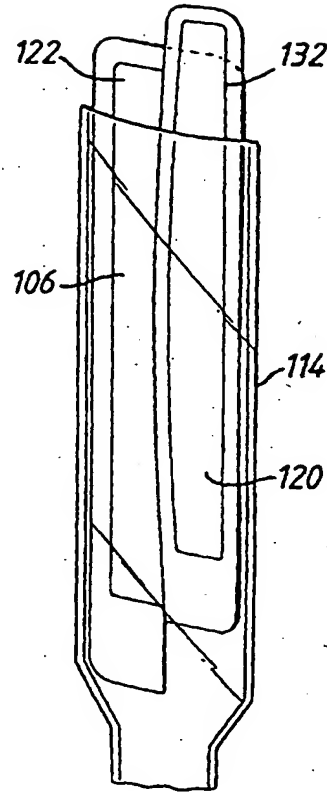
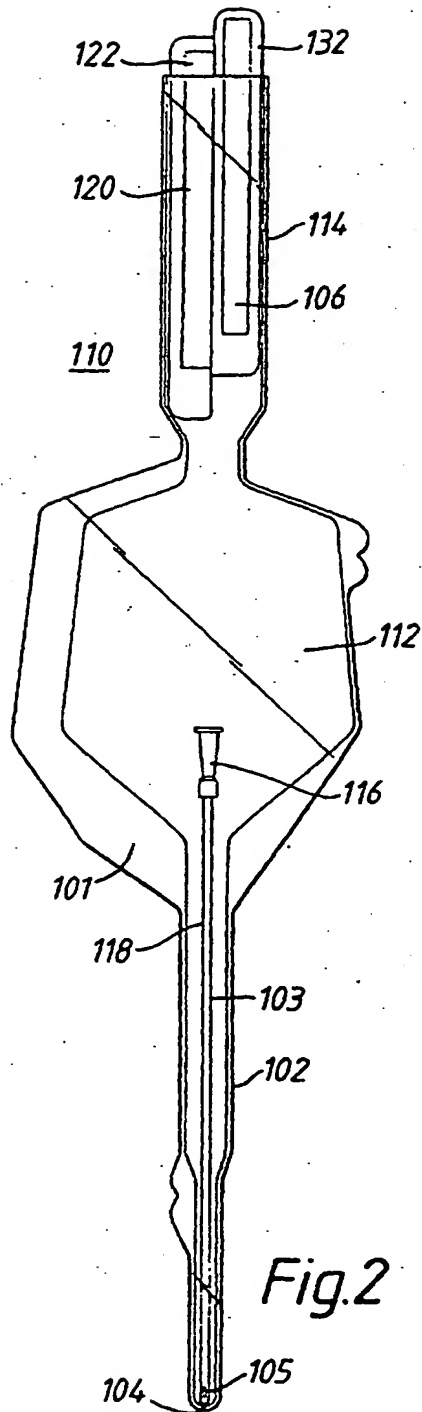


Fig. 1



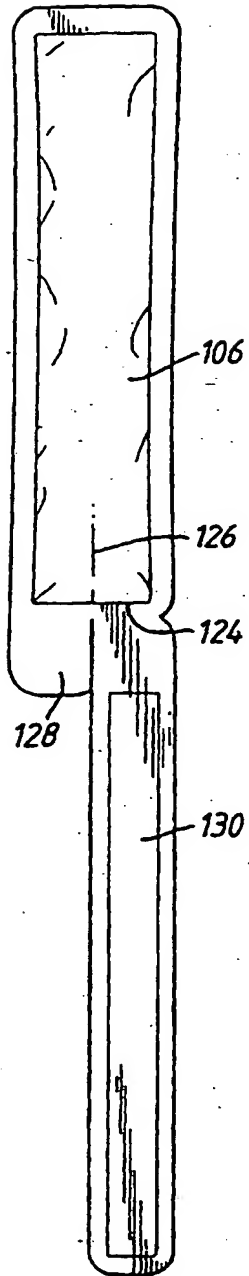


Fig. 4

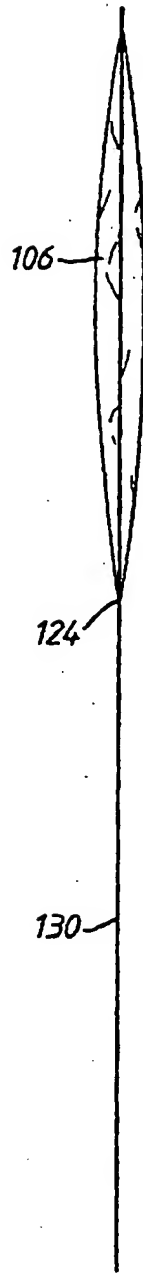


Fig. 5

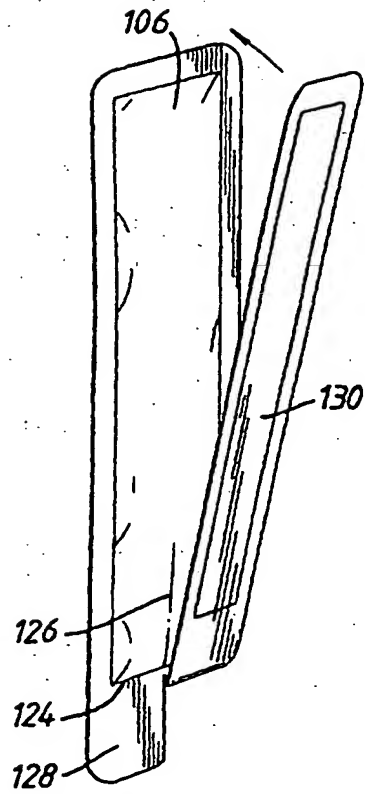


Fig. 6

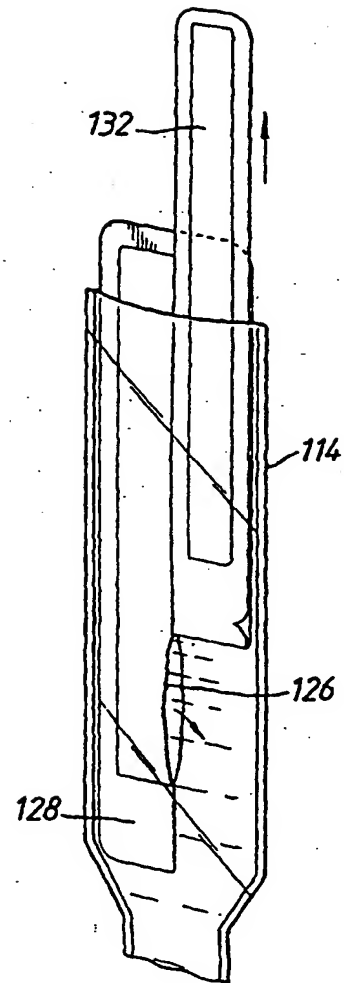
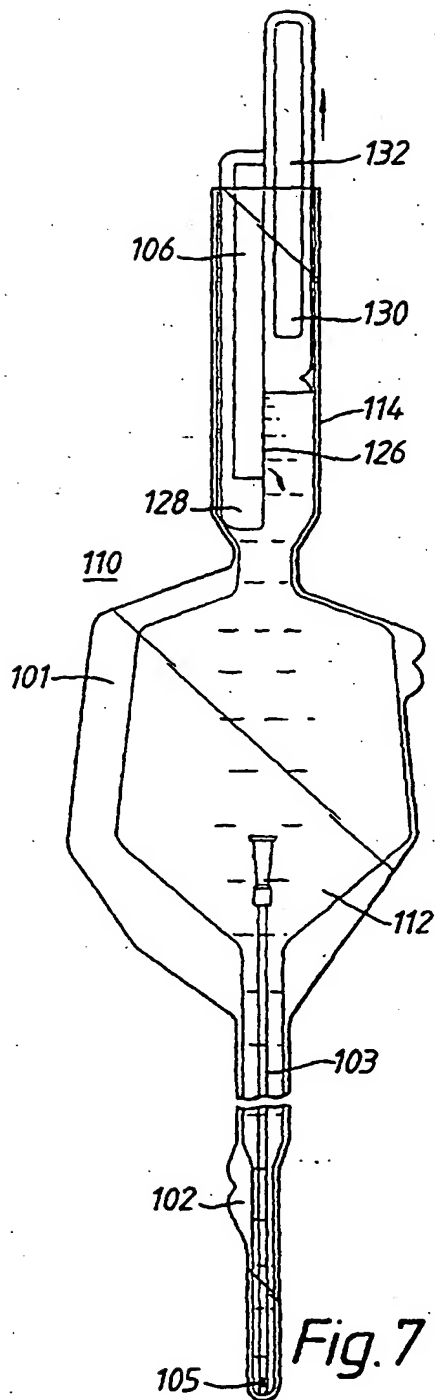


Fig. 8

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.